

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

VALUE DRUG COMPANY	:	CIVIL ACTION
	:	
v.	:	NO. 21-3500
	:	
TAKEDA PHARMACEUTICALS,	:	
U.S.A., INC., <i>et al.</i>	:	

ORDER - MEMORANDUM

AND NOW, this 25th day of April 2022, upon considering Watson Laboratories, Inc., Amneal Pharmaceuticals LLC, Teva Pharmaceuticals Industries, and Teva Pharmaceuticals USA, Inc.'s Motion for reconsideration or leave to file an interlocutory appeal (ECF Doc. No. 213) of our March 30, 2022 Order (ECF Doc. No. 207) granting in part and denying in part their joint Motion to Dismiss (ECF Doc. No. 169), Plaintiff's Response (ECF Doc. No. 240), and for reasons below, it is **ORDERED** the Motion for reconsideration or leave to file an interlocutory appeal (ECF Doc. No. 213) is **DENIED**.

Analysis

Generic Colcris manufacturers Watson Laboratories, Inc., Amneal Pharmaceuticals LLC, Teva Pharmaceuticals Industries, and Teva Pharmaceuticals USA, Inc. ask we reconsider our March 30, 2022 Order denying in part their joint Motion to dismiss a pharmacy buyer's antitrust claims against them.¹ They argue our March 30, 2022 Order rests on two mistaken factual premises: (1) we overstated the benefit they received from the conspiracy by suggesting their 135 days of limited competition was certain, not speculative; and (2) we misstated Watson and

¹ ECF Doc. No. 213-1 at 4. We refer to the moving parties as Watson and Amneal and write for the parties given their extensive familiarity with these issues more fully addressed in our December 29, 2021 and March 30, 2022 opinions. ECF Doc. Nos. 157, 207.

Amneal would not compete against Par's generic when they entered the market, but they in fact would have competed with Par under the terms of the settlement agreements. We are not persuaded by either argument. We also decline leave to file an interlocutory appeal.

A motion for reconsideration may only be granted where the moving party shows: "(1) an intervening change in the controlling law; (2) the availability of new evidence that was not available when the court granted the [previous] motion . . .; or (3) the need to correct a clear error of law or fact or to prevent manifest injustice."² Watson and Amneal argue we must grant the motion for reconsideration and dismiss the first amended class action Complaint against them because our reasoning rests on two incorrect, material factual statements. We disagree we misstated any fact as it relates to Watson and Amneal's first argument. And Watson and Amneal's second argument seems to rest either on our lack of clarity in, or their misunderstanding of, our March 30, 2022 opinion. We hope to make it as clear as we can: Watson and Amneal present fact issues inappropriate to resolve in their favor on a motion to dismiss. We decline to grant leave to file an interlocutory appeal as our March 30, 2022 Order does not raise a controlling question of law.

We correctly described the benefit of the limited competition period.

Watson and Amneal first argue we suggested "Amneal and Watson were certain to achieve 135 days of limited competition" but we are "indisputably mistaken" because "under the written terms of the settlement agreements themselves [] Amneal and Watson could enjoy 135 days of limited competition *only if* no other ANDA filer unilaterally entered the market unilaterally [*sic*], (*i.e.* without authorization from Takeda)."³ In essence, Watson and Amneal

² *Max's Seafood Café ex rel. Lou-Ann, Inc. v. Quinteros*, 176 F.3d 669, 677 (3d Cir. 1999).

³ ECF Doc. No. 213-1 at 7 (emphasis in original).

argue the “135-day limited competition period was only a possibility, not a certainty.”⁴ Watson and Amneal seize on our December 29, 2021 opinion recognizing Value Drug’s theory depended on (but the pleading failed to adequately plead or address) the non-conspiring generics staying off the market.⁵ We disagree our factual recitation is “indisputably mistaken” or it warrants a change in our finding. And Value Drug cured the deficiency raised in our December 29, 2021 opinion with its amended pleading.

Value Drug pleads substantial facts about this “Third Wave” of filers, including the possibility they could disrupt the conspiracy.⁶ But Value Drug pleads Takeda entered into settlement agreements with the Third Wave, which provided entry dates 135 days after Watson and Amneal and other entry date options just as the conspiring Generics had in their agreements.⁷ And Value Drug pleads the Third-Wave filers had no economic incentive to litigate their patent infringement suits with Takeda to verdict “when [their] only reward would be the entry of all other ANDA filers that had obtained FDA approval, including Amneal and Watson. In such circumstances, a Third Wave ANDA filer may not even recoup its litigation expenses by competing.”⁸ Value Drug adequately pleads facts ameliorating our previous concern about the plausibility of the conspiracy when not all market participants assented to it.

⁴ *Id.*

⁵ *Id.* at 7–8.

⁶ ECF Doc. No. 163 ¶¶ 126–128, 135–36.

⁷ *Id.* ¶¶ 127–28.

⁸ *Id.* ¶ 136.

We are also not persuaded by Watson and Amneal’s argument Mylan launching “at risk” purportedly proves the purely speculative benefit of the conspiracy.⁹ Value Drug pleads no other Third-Wave ANDA filer for Colcrys had an incentive to litigate costly patent infringement litigation to verdict which would cause them to settle with Takeda. And they did all in fact settle.¹⁰ It is clear from Value Drug’s pleading—and Takeda and Par’s actions—no one expected Mylan to argue, let alone succeed in arguing, a decision in the unrelated *Mitigare* litigation would permit Mylan to launch under its license agreement with Takeda.¹¹ Takeda and Par strenuously argued the *Mitigare* decision did not permit Mylan to launch while seeking a preliminary injunction to stop it and protect the aims of the conspiracy.¹²

We are satisfied based on Value Drug’s pleading Takeda and the Generics did not anticipate a Third-Wave filer would (1) litigate the patent infringement case to verdict, or (2) successfully argue a decision in unrelated litigation permits it to launch and thwart the aims of the conspiracy. That an unexpected event occurred to disrupt the conspiracy does not lead us conclude the conspiracy is implausible from the outset. And while Watson and Amneal suggest we “overstate” the value it received, we find Watson and Amneal grossly overstate the “speculative” benefit—if you can describe it as such—if the conspiracy continued. Value Drug’s pleading adequately addresses the Third-Wave ANDA filers and Mylan’s unexpected launch.

⁹ It is unclear if Mylan launched “at risk” as argued by Watson and Amneal. *Id.* ¶¶ 127(b)–(c), 160. Value Drug pleads Mylan launched under the “Final Court Provision” in its license agreement with Takeda. *Id.* ¶¶ 127(b)–(c), 160.

¹⁰ *Id.* ¶¶ 126–128, 135–36.

¹¹ *Id.*

¹² *Id.* ¶¶ 160–69.

We do not find Watson and Amneal's argument about the speculative nature of their benefit persuasive.

Watson and Amneal misunderstand our March 30 opinion.

Watson and Amneal next argue we incorrectly stated Watson and Amneal's benefit partially derived from only competing with Takeda's authorized generic sold through Par rather than Par's generic *and* Takeda's authorized generic sold through Prasco. Whether we misstated this fact is immaterial to our holding. Our holding does not change because Watson and Amneal's argument about motive or the conspiracy "making no economic sense" for them raises fact issues we cannot resolve in their favor on a motion to dismiss. We informed Watson and Amneal their argument may have merit on summary judgment in our previous opinion, but it is inappropriate to raise at this pleading stage. We find the same today.

Because it seems we may have sacrificed clarity for brevity in our previous opinion, we detail why we find fact issues in Watson and Amneal's argument here rather than summarily upholding our previous finding. Watson and Amneal argued in their Motion to dismiss Value Drug's pleaded conspiracy made no economic sense for them because "[u]nder [Value Drug's] own counterfactual, it is *likely* that the market would have remained a four-generic market *for some time* after any litigation victory and launch on the part of Watson and Amneal."¹³ They

¹³ ECF Doc. No. 169 at 17 (emphases added). They argue the same in the Motion for reconsideration. *See* ECF Doc. No. 213 at 10 ("On Plaintiff's own pleaded allegations of fact, then, and making all inferences in Plaintiff's favor, the most that Amneal and Watson could have hoped for, at the time of their settlements, would be to launch into a market that included *at least the same four* generics: Amneal, Watson, Par, and a Takeda AG." (emphasis added)). To the extent they now attempt to argue about Takeda launching a second authorized generic if Par launched, they did not raise this in their original Motion to dismiss (*see, e.g.*, ECF Doc. No. 169), and a Motion for reconsideration is not the appropriate vehicle to raise it. *See Gorgonzola v. Ahuja*, No. 10-01768, 2022 WL 796922, at *10 (W.D. Pa. Mar. 16, 2022) ("Furthermore, "[a] motion for reconsideration is not to be used as a way to advance additional arguments that the

continue: “Given the actual ‘timeline’ [Value Drug] pleads, *the most likely* litigation-victory scenario would have Amneal and Watson launching in January 2017 into a four-competitor market that would persist *significantly longer than* 135 days, until the FDA approved Mylan’s Fall 2016 ANDA which, given the *average approval times*, would not have occurred until 2018 at best.”¹⁴ In support of their theory, they ask us to take judicial notice of *average* approval times from October to December 2017 or a period in 2018.¹⁵

We emphasize Watson and Amneal’s own words because they illuminate abundant fact issues we cannot resolve at this stage. Watson and Amneal are today asking us to take judicial notice of *average* Food and Drug Administration approval times from fall 2017 or “some quarters” of 2018. They argue Value Drug’s pleaded theory is implausible because, based on these average timeframes, it is “likely” had Watson and Amneal won the patent litigation they actually would have competed against the same number of generics they allegedly conspired to compete with for 135 days, for “some time” “significantly longer than 135 days” and thus, received no benefit from the conspiracy.

Watson and Amneal’s use of statistics from “[r]elatively contemporaneous FDA reporting statistics from October-December 2017” and “some quarters in 2018” without further explanation is curious. And the statistics they hope we apply return us to grade school to

litigant could have made, but chose not to make, sooner, or as an opportunity for a litigant, having lost, to change theories of the case.”) (further citations omitted).

¹⁴ *Id.* (emphases added for text in bold and italics, italics only in original). We focus on Mylan despite there being multiple Third-Wave ANDA filers. We focus on Mylan as the first Third-Wave ANDA filer because if Mylan could have entered at or near when Watson and Amneal would have entered had they won the patent litigation, Watson and Amneal would have faced *more* competition than they faced with the conspiracy, lending credence to Value Drug’s pleaded motive for Watson and Amneal to enter the conspiracy.

¹⁵ *Id.* at 17 n.9.

differentiate between “mean” and “median,” as Watson and Amneal cite both mean times and median times but only argue about “averages.”¹⁶

First, Watson and Amneal cite the Administration’s statistics from fall 2017 and “some quarters” of 2018. But they do not attempt to tell us why those are the relevant time periods to review for this case. Value Drug pleads Mylan filed for ANDA approval in fall 2016, not fall 2017 or “some quarters” of 2018. We will not assume the relevance of the time period Watson and Amneal cite on a motion to dismiss.¹⁷

Second, Watson and Amneal argue about “averages” but cite statistics for both mean and median approval times.¹⁸ For example, Watson and Amneal argue “the average approval time for ANDAs was over 40 months” from October through December 2017 and while “some quarters in 2018 had shorter time periods, the best was over 22 months (669 days) on average.”¹⁹ But no quarter in 2018 had an average (or mean) approval time of twenty-two months.²⁰ There is, however, a quarter in 2018 which had a *median* approval time of 22.78 months. The difference is material.

¹⁶ ECF Doc. No. 169-1 at 17, 17 n.9 (directing us to <https://www.fda.gov/drugs/generic-drugs/activities-report-generic-drugs-program-fy-2018-gdufa-ii-quarterly-performance>).

¹⁷ Even if this is the correct and relevant time for us to consider, the statistics still raise fact issues which we cannot decide on a motion to dismiss.

¹⁸ ECF Doc. No. 169-1 at 17, 17 n.9 (solely arguing about “average” times).

¹⁹ *Id.*

²⁰ Food and Drug Administration, Activities Report of the Generic Drugs Program (FY 2018) | GDUFA II Quarterly Performance, <https://www.fda.gov/drugs/generic-drugs/activities-report-generic-drugs-program-fy-2018-gdufa-ii-quarterly-performance> (last visited Apr. 18, 2022).

The Administration reports “mean” approval times by quarter in 2018.²¹ Mean²² is a synonym of “average,”²³ which Watson and Amneal cite. The mean is calculated by adding the data points in a data set and dividing by the total number of data points in the set.²⁴ The Administration also reports the median approval time by quarter in 2018. A median is calculated differently than a mean. The median is “[l]ocated in or related to the precise midpoint in a range of values or quantities, such that half of them fall above the midpoint and half below.”²⁵ The median is calculated by arranging the data set in order of magnitude with the smallest number first, and then identifying the middle mark in the data set.²⁶

²¹ *Id.*

²² MEAN, Black’s Law Dictionary (11th ed. 2019) (“1. Of, relating to, or involving an intermediate point between two points or extremes <a mean position>. 2. Medium in size <a mean height>. 3. (Of a value, etc.) average <a mean score>.”); *see also* David M. Lane, *Introduction to Statistics*, 673 https://onlinestatbook.com/Online_Statistics_Education.pdf (last visited Apr. 20, 2022) (“**Mean** Also known as the arithmetic mean, the mean is typically what is meant by the word ‘average.’ The mean is perhaps the most common measure of central tendency. The mean of a variable is given by (the sum of all its values)/(the number of values).”); Michael O. Finkelstein & Bruce Levin, *Statistics for Lawyers*, Section 1.2 Measures of Central Location 3 (2nd ed. 2001) (“By far the most common measure of location for sample data is the familiar ‘average,’ or arithmetic mean . . . The mean in a sample is computed in the same way as the population mean, i.e., it is the sum of the sample values divided by the sample size.”)

²³ AVERAGE, Black’s Law Dictionary (11th ed. 2019) (“1. A single value that represents the midpoint of a broad sample of subjects; esp., in mathematics, the mean of a series. 2. The ordinary or typical level; the norm.”).

²⁴ *See supra* n.22.

²⁵ MEDIAN, Black’s Law Dictionary (11th ed. 2019) (emphasis added); *see also* Lane, *supra* at 673 (“**Median** The median is a popular measure of central tendency. It is the 50th percentile of a distribution. To find the median of a number of values, first order them, then find the observation in the middle: the median of 5, 2, 7, 9, and 4 is 5. (Note that if there is an even number of values, one takes the average of the middle two: the median of 4, 6, 8, and 10 is 7.)”); Finkelstein & Levin, *supra*, at 4 (“The *median* . . . is any value such that at least half of the values lie at or above and at least half lie at or below it.”).

²⁶ *See supra* n.25.

Regardless of the data we examine, Watson and Amneal’s argument raises fact issues we cannot resolve in their favor on a motion to dismiss. The Administration’s very use of a mean implies approval could take longer or shorter than the mean time.²⁷ Even more problematic to Watson and Amneal’s argument is their reliance on the median time. With a median of 22.78 months for approval, we know half of the ANDA applications received approval faster than 22.78 months during this quarter in 2018. We do not know the fastest approval from either data set—average or median.²⁸ But we certainly cannot take this median figure of approximately twenty-two months for one quarter in 2018 and conclude it is implausible Mylan (or any other

For example, if our data set consisted of:

8	14	15	19	21	25	36	45	65
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- the mean would be 27.5 (approximately); and
- the median would be 21.

²⁷ The Administration also tells us how it calculates the data points it uses in its chart. *See* Food and Drug Administration, Activities Report of the Generic Drugs Program (FY 2018) | GDUFA II Quarterly Performance, <https://www.fda.gov/drugs/generic-drugs/activities-report-generic-drugs-program-fy-2018-gdufa-ii-quarterly-performance> (last visited Apr. 18, 2022) (“**Mean/ Median AP/TA Time** is calculated as the difference between the first full approval (AP) date or the first Tentative Approval (TA) date and the date the original application was accepted for filing divided by the average number of days per month (30.4375). The unit for each of these metrics is months.”).

²⁸ We note counsel for Watson and Amneal argued this “twenty-two month” figure is *the fastest* time to get approval at oral argument. ECF Doc. No. 206, Redacted Oral Argument Transcript (Tr.), Mar. 10, 2022, at 37:18–40:15. This contradicts their briefing where they argued “the best was 22 months . . . *on average*” during “some quarters” in 2018, *see* ECF Doc. No. 169 at 17 n.9) (emphasis added), and also contradicts the Administration’s statistics which Watson and Amneal cite, which show 22.78 months as a *median*, not the mean or the fastest. Food and Drug Administration, Activities Report of the Generic Drugs Program (FY 2018) | GDUFA II Quarterly Performance, <https://www.fda.gov/drugs/generic-drugs/activities-report-generic-drugs-program-fy-2018-gdufa-ii-quarterly-performance> (last visited Apr. 18, 2022). Watson and Amneal do not cite a statistic showing the fastest approval the Administration has *ever* given is twenty-two months. And we doubt such a statistic exists considering our earlier discussion about median calculation.

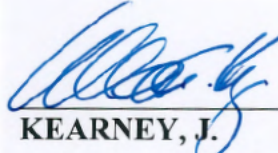
Third-Wave filer) would have received approval in faster than twenty-two months when we know half of the ANDA filers during this quarter in 2018 did so.

We cannot resolve fact issues raised by Watson and Amneal’s counter to Value Drug’s pleaded counterfactual at this stage. As we stated in our previous opinion, these fact issues prevent us from granting Watson and Amneal’s motion to dismiss. We conclude Value Drug pleads a plausible counter factual scenario of what would have happened but for the conspiracy, which together with its other pleaded facts we detailed in our March 30, 2022 opinion, sufficiently describes a plausible motive for Watson and Amneal to conspire. Watson and Amneal want us to find their counter to Value Drug’s counterfactual—filled with unknowns, generalities, and likelihoods—makes Value Drug’s pleaded motive implausible. We cannot do so at this stage. It is Value Drug’s burden to prove its pleaded motive at summary judgment and trial if warranted. For now, Value Drug adequately pleads a plausible motive belying Watson and Amneal’s argument about economic implausibility. Our previous holding need not be reconsidered because the fact issues raised by Watson and Amneal’s argument formed the basis of our previous opinion although we did not spell them out. Our holding remains the same irrespective of a perceived “misstatement” of fact.²⁹

²⁹ Value Drug pleads Watson and Amneal’s benefit derived from “[c]ompeting against just Par and Takeda for 135 days” rather than “up to 21 potential competitors.” ECF Doc. No. 163 ¶ 134. And we recognize under the license agreements Par *could* launch its generic when Watson and Amneal launched theirs. The parties now seem to quibble about Par’s incentive to launch its generic when Watson and Amneal did so and the price collapse which occurs with each additional generics’ launch. We need not reach this issue today. **Assuming** a four-entrant market, which is the basis of Watson and Amneal’s argument, there are fact issues (now detailed extensively in this opinion) which prevent a finding Watson and Amneal would have entered into the same four-entrant market without the conspiracy and thus received no benefit.

Watson and Amneal do not state a basis for an interlocutory appeal.

Watson and Amneal's request for an interlocutory appeal is based on a misreading of our opinion as "blindly" accepting Value Drug's motive as plausible.³⁰ They argue we cannot blindly accept Value Drug's pleaded motive; rather, we must compare it to what would have happened without the conspiracy to determine plausibility. We did so. We compared the pleaded benefit of 135 days of limited competition to Value Drug's pleaded counterfactual of what would have happened absent the conspiracy. We found a plausible motive. Watson and Amneal's counter to the pleaded counterfactual raises fact issues we cannot resolve on a motion to dismiss. There is no controlling issue of law to decide through an interlocutory appeal.



KEARNEY, J.

³⁰ Watson and Amneal request an interlocutory appeal under 28 U.S.C. § 1292(b), which provides: "When a district judge, in making in a civil action an order not otherwise appealable under this section, shall be of the opinion that such order involves a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the litigation, he shall so state in writing in such order." 28 U.S.C. § 1292(b); *see also Nat'l Liab. & Fire Ins. Co. v. Brimar Transit, Inc.*, No. 18-1129, 2021 WL 6098288, at *2 (W.D. Pa. Dec. 23, 2021) ("Certification pursuant to § 1292(b) should be granted 'sparingly' and only when three conditions are met: (1) where immediate appeal may avoid protracted and expensive litigation, (2) the request involves a controlling question of law, and (3) where there is a substantial basis for differing opinion.") (further citations and internal quotations omitted).